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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/755,016	01/05/2001	D. Wade Walke	LEX-0114-USA	4538

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LEXICON GENETICS INCORPORATED  
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THE WOODLANDS, TX 77381-1160

EXAMINER

FRONDA, CHRISTIAN L.

ART UNIT	PAPER NUMBER
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1652

15

DATE MAILED: 03/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.  
**09/755,016**

Applicant(s)  
**Walke et al.**

Examiner  
**Christian L. Fronda**

Art Unit  
**1652**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☒ This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 2, and 5-10 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, and 5-10 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are a) \_\_\_\_\_ accepted or b) \_\_\_\_\_ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) \_\_\_\_\_ approved b) \_\_\_\_\_ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some\* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in the \_\_\_\_\_.

Attachment(s)

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### DETAILED ACTION

1. Claims 1, 2, and 5-10 are under consideration in this Office Action.

#### *Claim Rejections - 35 U.S.C. § 101*

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1, 2, and 5-10 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Applicants' arguments filed December 4, 2002 (Paper No. 14) have been fully considered but they are not persuasive. Applicants' position is that since GenBank accession number XM\_171629 has 100% identity at the amino acid level "over an extended region" of the deduced amino acid sequence of SEQ ID NO: 4 then one skilled in the art would recognize that Applicants' sequence is a protease and that the claimed invention has a substantial, specific, credible, and well established utility. The Examiner disagrees for the reasons stated below.

Attwood et al. (Comput. Chem. 2001, Vol. 25(4), pp. 329-39) teach that "...we do not fully understand the rules of protein folding, so we cannot predict protein structure; and we cannot invariably diagnose protein function, given knowledge only of its sequence or structure in isolation" (see Abstract and entire publication). Furthermore, Ponting (Brief. Bioinform. March 2001, Vol. 2(1), pp. 19-29) states that "...predicting function by homology is a qualitative, rather than quantitative, process and requires particular care to be taken...due attention should be paid to all available clues to function, including orthologue identification, conservation of particular residue types, and the co-occurrence of domains in proteins" (See Abstract and entire publication).

The annotation for GenBank accession number XM\_171629 as shown in **Exhibit C** and **Exhibit D** indicates that the protein which has 100% identity at the amino acid level "over an extended region" of the deduced amino acid sequence of SEQ ID NO: 4 is "similar to cortical granule serine protease 1", but does not state that XM\_171629 is a protein that has any serine protease activity. **Exhibit C** and **Exhibit D** are attached to this Office Action.

The specification discloses that the protein, consisting of SEQ ID NO: 4 is a "novel human protein (NHPP) sharing structural similarity with "trypsin-like serine proteases" which is a generic

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asserted utility.

It appears that the main utility of the nucleic acids and protein is to carry out further research to identify the biological function and possible diseases associated with the nucleic acids and protein. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utility. Thus, the claimed invention has no specific and substantial asserted utility or a well established utility.

Claims 1, 2, and 5-10 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

***Claim Rejections - 35 U.S.C. § 112, 1st Paragraph***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 1 and 7-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' arguments filed December 4, 2002 (Paper No. 14) have been fully considered but they are not persuasive. Applicants' position is that the claims meet the written description requirement and that a skilled artisan would be able to distinguish the claimed nucleic acids from other materials based on the structural features and structural description provided, specifically, the nucleotide sequence of SEQ ID NO: 3, 60 contiguous nucleotides of SEQ ID NO: 3, and the nucleotide sequence that encodes the amino acid sequence of SEQ ID NO: 4 are within the genus of the invention and that nucleic acids that lack the structural features are not included in the genus.

The specification provided no clear specification of the structural features of the particular structure to function activity relationship in the disclosed species. The claims are directed to all possible polynucleotides comprising at least 60 contiguous nucleotides of SEQ ID NO: 3 of any function

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or utility and encoding any protein/enzyme of any activity which are not described in the specification. Furthermore, the specification does not provide a written description of the nucleotide sequence that is 5' or 3' of 60 contiguous nucleotides of SEQ ID NO: 3. Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention. Claims 7-10 which depend from claim 1 are also rejected because they do not correct the defect of claim 1. Amending the claim to recite that the claimed nucleic acid encodes a specific enzyme may overcome this rejection.

### *Conclusion*

6. No claim is allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. The Examiner can be contacted Monday-Friday from 8:30AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.